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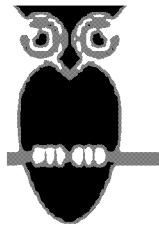
Quarterly Compliance Report to Board of Directors for 2Q2015

Bert Weinstein
Vice President, Corporate Compliance
August 20, 2015



U.S. - 30

Bottom Line



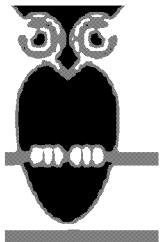
Purdue continues to have strong systems and processes in place to prevent and detect violations of law, regulations, and Company policies, and to remediate issues before they become significant problems.

There have been no significant compliance issues in the 2nd quarter, 2015

This report focuses on the Office of Inspector General's (OIG) updated Guidance for Compliance Oversight by Health Care Boards (attached for reference), with updates on the Sunshine Act and a compliance audit



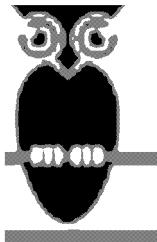
U.S. - 31



2015 Sunshine Act filing (2014 data)

- Purdue's 2015 report timely reported March 30th
- Total Purdue HCP and Teaching hospital spend for 2014 was \$24 million
 - "Research Spend" = \$16.3 million (research spend is not made public for up to four years)
 - "General Spend" = \$7.7 million made public (e.g., consulting, speaker programs, meals)
- Spend data for all pharma and device companies was published by CMS on June 30th
- Disputes – All 97 disputes filed during the CMS dispute resolution period were resolved amicably, with no negative impact
- No media stories on Purdue to date





Compliance Audit

During Q2, an audit was conducted to explore whether HCP prescribing might have been influenced by consulting payments or other value received from Purdue

- Reviewed 100 highest *prescribers* of Butrans, 100 highest prescribers of OxyContin, and 100 highest *Purdue-compensated* HCPs in 2014
- *Results – There was no correlation found between Purdue’s financial relationships with HCPs and their prescribing of Purdue products*
- For the 10 out of 200 “overlapping” HCPs that were both among the highest prescribers and the highest recipients of Purdue compensation, a deeper review indicated that their prescribing of Purdue products was consistent with their prescribing of other long-acting opioids, *eliminating concerns that Purdue compensation improperly affected prescribing*

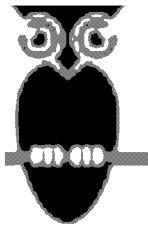


U.S. - 33

OIG's Guidance for Health Care Boards on Compliance Oversight



U.S. - 34

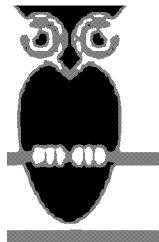


Summary

- From time to time, the Office of Inspector General of HHS issues guidances to industry. Guidances do not carry the force of law or regulations, but do serve as a window into the OIG's thinking about best practices. This update of their original 2003 guidance suggests means for health care boards to provide effective compliance oversight, including:
 - General expectations for board oversight of a compliance program
 - Defining roles and relationships related to compliance oversight
 - Reporting of compliance-related information to the board
 - Identification and auditing of potential risks
 - Encouraging accountability and compliance in an organization
- The following slides represent the views of OIG. The Guidance is attached for reference.



Expectations for Board Oversight

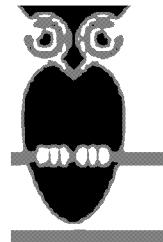


Boards should be engaged in oversight of the compliance program

- Boards should ask the right questions of management to determine the effectiveness of the organization's compliance program
- Boards may benchmark company compliance programs against the Federal Sentencing Guidelines, OIG's Compliance Guidance for the Pharmaceutical Industry, and current OIG Corporate Integrity Agreements; ensuring management awareness of these resources is "a good first step"
- Boards may consider plans to stay abreast of the evolving compliance environment, such as updates from staff, to assure adequate resources
- Boards may want to consult with experienced regulatory, compliance or legal professionals



Roles and Relationships

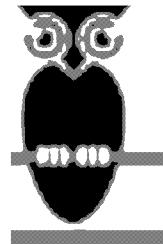


Organizations should define the functions of audit, compliance, legal, quality, and HR

- While independent, compliance, legal, audit, quality, and HR functions should cooperate and collaborate with each other
- The attorney-client privilege should be balanced against the need for information access, reporting and remediation of violations by key individuals responsible for compliance
- Boards should have a process to ensure access to information
- Boards should understand how management works together to identify compliance risks, investigate failures, communicate effectively, and implement corrective actions



Reporting Information to the Board

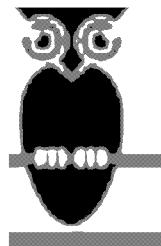


The Board should set expectations and receive appropriate and timely information relating to compliance with applicable laws

- Boards should receive regular reports from a variety of key players, including audit, compliance, HR, Law, Quality, and IT functions
- Boards may request information concerning objective scorecards, investigations, audits, hotline activity, allegations of management misconduct, etc.
- Boards should create an expectation of open dialogue with compliance, legal, audit, and quality functions, and may consider “executive sessions” with senior management not present



Identifying and auditing potential risks



The Board should ensure that management and the Board have strong processes for identifying compliance risks

- Boards may identify risks from internal information sources, including audits, hotlines, and external sources, such as OIG issued guidances, consultants, news media, other company failures
- Boards should ensure that management consistently reviews and monitors risk areas, and develops corrective action plans
- New industry trends should be considered in assessing risk – new forms of health plans, payment models, transparency



Encouraging Accountability and Compliance

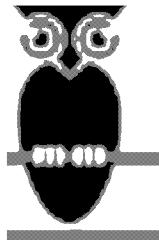


It is the responsibility of the entire organization to execute the compliance program

- Boards may assess compliance-related performance at individual, departmental and facility levels as a basis for compensation decisions, including withholding of incentives or bonuses
- Self-reporting of compliance violations to the Government is encouraged
- Boards may evaluate whether compliance processes encourage effective communication, so that employees feel confident raising issues without fear of retaliation



U.S. - 40



Our Views

- Purdue's compliance program is regularly updated to account for regulatory guidance, including the Sentencing Guidelines, OIG's Compliance Guidance, and CIAs. Our quarterly reports speak to the evolving compliance environment, and seek to keep the Board well-informed of the status of compliance at Purdue, including any significant developments.
- We have a robust risk assessment process that is owned by the business units, updated quarterly, and reviewed by Purdue's senior executive-level compliance council to ensure collaboration, and includes robust auditing and monitoring of key compliance risks.
- The Purdue organization is well trained, sensitive to good compliance practices, and comfortable communicating with the Compliance department.
- We believe have no recommendations for altering practices as a result of this Guidance, will keep you informed of any developments, and will welcome any inquiries from you.



Blue Sheet

U.S. - 42



Practical Guidance for Health Care Governing Boards on Compliance Oversight

Office of Inspector General,
U.S. Department of Health and Human Services
Association of Healthcare Internal Auditors
American Health Lawyers Association
Health Care Compliance Association

About the Organizations

This educational resource was developed in collaboration between the Association of Healthcare Internal Auditors (AHIA), the American Health Lawyers Association (AHLA), the Health Care Compliance Association (HCCA), and the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS).

AHIA is an international organization dedicated to the advancement of the health care internal auditing profession. The AHLA is the Nation's largest nonpartisan, educational organization devoted to legal issues in the health care field. HCCA is a member-based, nonprofit organization serving compliance professionals throughout the health care field. OIG's mission is to protect the integrity of more than 100 HHS programs, including Medicare and Medicaid, as well as the health and welfare of program beneficiaries.

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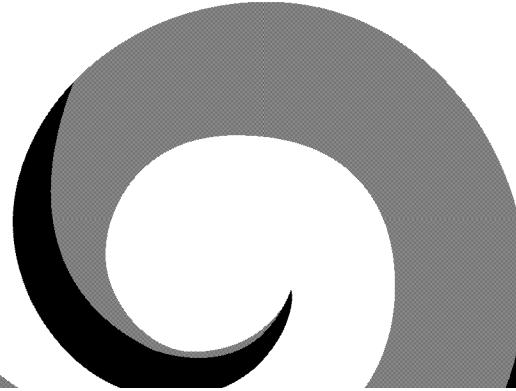
This document is intended to assist governing boards of health care organizations (Boards) to responsibly carry out their compliance plan oversight obligations under applicable laws. This document is intended as guidance and should not be interpreted as setting any particular standards of conduct. The authors recognize that each health care entity can, and should, take the necessary steps to ensure compliance with applicable Federal, State, and local law. At the same time, the authors also recognize that there is no uniform approach to compliance. No part of this document should be taken as the opinion of, or as legal or professional advice from, any of the authors or their respective agencies or organizations.

Table of Contents

Introduction	1
Expectations for Board Oversight of Compliance Program Functions	2
Roles and Relationships	6
Reporting to the Board	9
Identifying and Auditing Potential Risk Areas	11
Encouraging Accountability and Compliance	13
Conclusion	15
Bibliography	16



U.S. - 45



Introduction

Previous guidance¹ has consistently emphasized the need for Boards to be fully engaged in their oversight responsibility. A critical element of effective oversight is the process of asking the right questions of management to determine the adequacy and effectiveness of the organization's compliance program, as well as the performance of those who develop and execute that program, and to make compliance a responsibility for all levels of management. Given heightened industry and professional interest in governance and transparency issues, this document seeks to provide practical tips for Boards as they work to effectuate their oversight role of their organizations' compliance with State and Federal laws that regulate the health care industry. Specifically, this document addresses issues relating to a Board's oversight and review of compliance program functions, including the: (1) roles of, and relationships between, the organization's audit, compliance, and legal departments; (2) mechanism and process for issue-reporting within an organization; (3) approach to identifying regulatory risk; and (4) methods of encouraging enterprise-wide accountability for achievement of compliance goals and objectives.

A critical element of effective oversight is the process of asking the right questions....

¹ OIG and AHLA, *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors* (2003); OIG and AHLA, *An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors* (2004); and OIG and AHLA, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (2007).

Expectations for Board Oversight of Compliance Program Functions

A Board must act in good faith in the exercise of its oversight responsibility for its organization, including making inquiries to ensure: (1) a corporate information and reporting system exists and (2) the reporting system is adequate to assure the Board that appropriate information relating to compliance with applicable laws will come to its attention timely and as a matter of course.² The existence of a corporate reporting system is a key compliance program element, which not only keeps the Board informed of the activities of the organization, but also enables an organization to evaluate and respond to issues of potentially illegal or otherwise inappropriate activity.

Boards are encouraged to use widely recognized public compliance resources as benchmarks for their organizations. The Federal Sentencing Guidelines (Guidelines),³ OIG's voluntary compliance program guidance documents,⁴ and OIG Corporate Integrity Agreements (CIAs) can be used as baseline assessment tools for Boards and management in determining what specific functions may be necessary to meet the requirements of an effective compliance program. The Guidelines "offer incentives to organizations to reduce and ultimately eliminate criminal conduct by providing a structural foundation from which an organization may self-police its own conduct through an effective compliance and ethics program."⁵ The compliance program guidance documents were developed by OIG to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. CIAs impose specific structural and reporting requirements to

2 *In re Caremark Int'l, Inc. Derivative Litig.*, 698 A.2d 959 (Del. Ch. 1996).

3 U.S. Sentencing Commission, *Guidelines Manual* (Nov. 2013) (USSG), http://www.ussc.gov/sites/default/files/pdf/guidelines-manual/2013/manual-pdf/2013_Guidelines_Manual_Full.pdf.

4 OIG, *Compliance Guidance*, <http://oig.hhs.gov/compliance/compliance-guidance/index.asp>.

5 USSG Ch. 8, Intro. Comment.

promote compliance with Federal health care program standards at entities that have resolved fraud allegations.

Basic CIA elements mirror those in the Guidelines, but a CIA also includes obligations tailored to the organization and its compliance risks. Existing CIAs may be helpful resources for Boards seeking to evaluate their organizations' compliance programs. OIG has required some settling entities, such as health systems and hospitals, to agree to Board-level requirements, including annual resolutions. These resolutions are signed by each member of the Board, or the designated Board committee, and detail the activities that have been undertaken to review and oversee the organization's compliance with Federal health care program and CIA requirements. OIG has not required this level of Board involvement in every case, but these provisions demonstrate the importance placed on Board oversight in cases OIG believes reflect serious compliance failures.

Although compliance program design is not a “one size fits all” issue, Boards are expected to put forth a meaningful effort....

Although compliance program design is not a “one size fits all” issue, Boards are expected to put forth a meaningful effort to review the adequacy of existing compliance systems and functions. Ensuring that management is aware of the Guidelines, compliance program guidance, and relevant CIAs is a good first step.

One area of inquiry for Board members of health care organizations should be the scope and adequacy of the compliance program in light of the size and complexity of their organizations. The Guidelines allow for variation according to “the size of the organization.”⁶ In accordance with the Guidelines,

⁶ USSG § 8B2.1, comment. (n. 2).

OIG recognizes that the design of a compliance program will depend on the size and resources of the organization.⁷ Additionally, the complexity of the organization will likely dictate the nature and magnitude of regulatory impact and thereby the nature and skill set of resources needed to manage and monitor compliance.

While smaller or less complex organizations must demonstrate the same degree of commitment to ethical conduct and compliance as larger organizations, the Government recognizes that they may meet the Guidelines requirements with less formality and fewer resources than would be expected of larger and more complex organizations.⁸ Smaller organizations may meet their compliance responsibility by “using available personnel, rather than employing separate staff, to carry out the compliance and ethics program.” Board members of such organizations may wish to evaluate whether the organization is “modeling its own compliance and ethics programs on existing, well-regarded compliance and ethics programs and best practices of other similar organizations.”⁹ The Guidelines also foresee that Boards of smaller organizations may need to become more involved in the organizations’ compliance and ethics efforts than their larger counterparts.¹⁰

Boards should develop a formal plan to stay abreast of the ever-changing regulatory landscape and operating environment. The plan may involve periodic updates from informed staff or review of regulatory resources made available to them by staff. With an understanding of the dynamic regulatory environment, Boards will be in a position to ask more pertinent questions of management

⁷ Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434, 59436 (Oct. 5, 2000) (“The extent of implementation [of the seven components of a voluntary compliance program] will depend on the size and resources of the practice. Smaller physician practices may incorporate each of the components in a manner that best suits the practice. By contrast, larger physician practices often have the means to incorporate the components in a more systematic manner.”); Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289 (Mar. 16, 2000) (recognizing that smaller providers may not be able to outsource their screening process or afford to maintain a telephone hotline).

⁸ USSG § 8B2.1, comment. (n. 2).

⁹ *Id.*

¹⁰ *Id.*

and make informed strategic decisions regarding the organizations' compliance programs, including matters that relate to funding and resource allocation. For instance, new standards and reporting requirements, as required by law, may, but do not necessarily, result in increased compliance costs for an organization. Board members may also wish to take advantage of outside educational programs that provide them with opportunities to develop a better understanding of industry risks, regulatory requirements, and how effective compliance and ethics programs operate. In addition, Boards may want management to create a formal education calendar that ensures that Board members are periodically educated on the organizations' highest risks.

Finally, a Board can raise its level of substantive expertise with respect to regulatory and compliance matters by adding to the Board, or periodically consulting with, an experienced regulatory, compliance, or legal professional. The presence of a professional with health care compliance expertise on the Board sends a strong message about the organization's commitment to compliance, provides a valuable resource to other Board members, and helps the Board better fulfill its oversight obligations. Board members are generally entitled to rely on the advice of experts in fulfilling their duties.¹¹ OIG sometimes requires entities under a CIA to retain an expert in compliance or governance issues to assist the Board in fulfilling its responsibilities under the CIA.¹² Experts can assist Boards and management in a variety of ways, including the identification of risk areas, provision of insight into best practices in governance, or consultation on other substantive or investigative matters.

11 See Del Code Ann. tit. 8, § 141(e) (2010); ABA Revised Model Business Corporation Act, §§ 8.30(e), (f)(2) Standards of Conduct for Directors.

12 See Corporate Integrity Agreements between OIG and Halifax Hospital Medical Center and Halifax Staffing, Inc. (2014, compliance and governance); Johnson & Johnson (2013); Dallas County Hospital District d/b/a Parkland Health and Hospital System (2013, compliance and governance); Forest Laboratories, Inc. (2010); Novartis Pharmaceuticals Corporation (2010); Ortho-McNeil-Janssen Pharmaceuticals, Inc. (2010); Synthes, Inc. (2010, compliance expert retained by Audit Committee); The University of Medicine and Dentistry of New Jersey (2009, compliance expert retained by Audit Committee); Quest Diagnostics Incorporated (2009); Amerigroup Corporation (2008); Bayer HealthCare LLC (2008); and Tenet Healthcare Corporation (2006; retained by the Quality, Compliance, and Ethics Committee of the Board).

Roles and Relationships

Organizations should define the interrelationship of the audit, compliance, and legal functions in charters or other organizational documents. The structure, reporting relationships, and interaction of these and other functions (e.g., quality, risk management, and human resources) should be included as departmental roles and responsibilities are defined. One approach is for the charters to draw functional boundaries while also setting an expectation of cooperation and collaboration among those functions. One illustration is the following, recognizing that not all entities may possess sufficient resources to support this structure:



The compliance function promotes the prevention, detection, and resolution of actions that do not conform to legal, policy, or business standards. This responsibility includes the obligation to develop policies and procedures that provide employees guidance, the creation of incentives to promote employee compliance, the development of plans to improve or sustain compliance, the development of metrics to measure execution (particularly by management) of the program and implementation of corrective actions, and the development of reports and dashboards that help management and the Board evaluate the effectiveness of the program.

The legal function advises the organization on the legal and regulatory risks of its business strategies, providing advice and counsel to management and the Board about relevant laws and regulations that govern, relate to, or impact the organization. The function also defends the organization in legal proceedings and initiates legal proceedings against other parties if such action is warranted.

The internal audit function provides an objective evaluation of the existing risk and internal control systems and framework within an organization. Internal audits ensure monitoring functions are working as intended and identify where management monitoring and/or additional

Board oversight may be required. Internal audit helps management (and the compliance function) develop actions to enhance internal controls, reduce risk to the organization, and promote more effective and efficient use of resources. Internal audit can fulfill the auditing requirements of the Guidelines.

The human resources function manages the recruiting, screening, and hiring of employees; coordinates employee benefits; and provides employee training and development opportunities.

The quality improvement function promotes consistent, safe, and high quality practices within health care organizations. This function improves efficiency and health outcomes by measuring and reporting on quality outcomes and recommends necessary changes to clinical processes to management and the Board. Quality improvement is critical to maintaining patient-centered care and helping the organization minimize risk of patient harm.

Boards should be aware of, and evaluate, the adequacy, independence,¹³ and performance of different functions within an organization on a periodic basis. OIG believes an organization's Compliance Officer should neither be counsel for the provider, nor be subordinate in function or position to counsel or the legal department, in any manner.¹⁴ While independent, an organization's counsel and compliance officer should collaborate to further the interests of the organization. OIG's position on separate compliance and legal functions reflects the independent roles and professional obligations of each function;¹⁵

13 Evaluation of independence typically includes assessing whether the function has uninhibited access to the relevant Board committees, is free from organizational bias through an appropriate administrative reporting relationship, and receives fair compensation adjustments based on input from any relevant Board committee.

14 See OIG and AHLA, *An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors*, 3 (2004) (citing Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987, 8,997 (Feb. 23, 1998)).

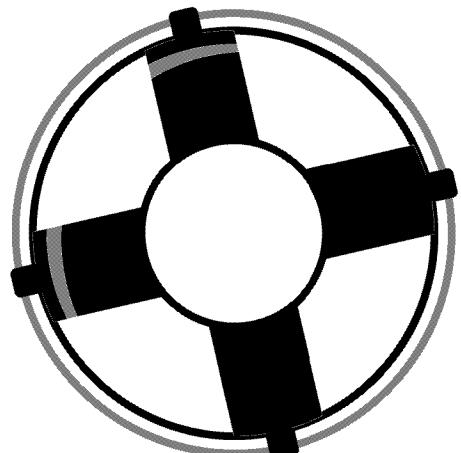
15 See, generally, *id.*

the same is true for internal audit.¹⁶ To operate effectively, the compliance, legal, and internal audit functions should have access to appropriate and relevant corporate information and resources. As part of this effort, organizations will need to balance any existing attorney-client privilege with the goal of providing such access to key individuals who are charged with the responsibility for ensuring compliance, as well as properly reporting and remediating any violations of civil, criminal, or administrative law.

The Board should have a process to ensure appropriate access to information; this process may be set forth in a formal charter document approved by the Audit Committee of the Board or in other appropriate documents. Organizations that do not separate these functions (and some organizations may not have the resources to make this complete separation) should recognize the potential risks of such an arrangement. To partially mitigate these potential risks, organizations should provide individuals serving in multiple roles the capability to execute each function in an independent manner when necessary, including through reporting opportunities with the Board and executive management.

Boards should also evaluate and discuss how management works together to address risk, including the role of each in:

1. identifying compliance risks,
2. investigating compliance risks and avoiding duplication of effort,
3. identifying and implementing appropriate corrective actions and decision-making, and
4. communicating between the various functions throughout the process.



¹⁶ Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987, 8,997 (Feb. 23, 1998) (auditing and monitoring function should “[b]e independent of physicians and line management”); Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42,410, 42,424 (Aug. 7, 1998) (auditing and monitoring function should “[b]e objective and independent of line management to the extent reasonably possible”); Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289, 14,302 (Mar. 16, 2000).

Boards should understand how management approaches conflicts or disagreements with respect to the resolution of compliance issues and how it decides on the appropriate course of action. The audit, compliance, and legal functions should speak a common language, at least to the Board and management, with respect to governance concepts, such as accountability, risk, compliance, auditing, and monitoring. Agreeing on the adoption of certain frameworks and definitions can help to develop such a common language.

Reporting to the Board

The Board should set and enforce expectations for receiving particular types of compliance-related information from various members of management. The Board should receive regular reports regarding the organization's risk mitigation and compliance efforts—separately and independently—from a variety of key players, including those responsible for audit, compliance, human resources, legal, quality, and information technology. By engaging the leadership team and others deeper in the organization, the Board can identify who can provide relevant information about operations and operational risks. It may be helpful and productive for the Board to establish clear expectations for members of the management team and to hold them accountable for performing and informing the Board in accordance with those expectations. The Board may request the development of objective scorecards that measure how well management is executing the compliance program, mitigating risks, and implementing corrective action plans. Expectations could also include reporting information on internal and external investigations, serious issues raised in internal and external audits, hotline call activity, all allegations of material fraud or senior management misconduct, and all management exceptions to the organization's

The Board should receive regular reports regarding the organization's risk mitigation and compliance efforts....

code of conduct and/or expense reimbursement policy. In addition, the Board should expect that management will address significant regulatory changes and enforcement events relevant to the organization's business.

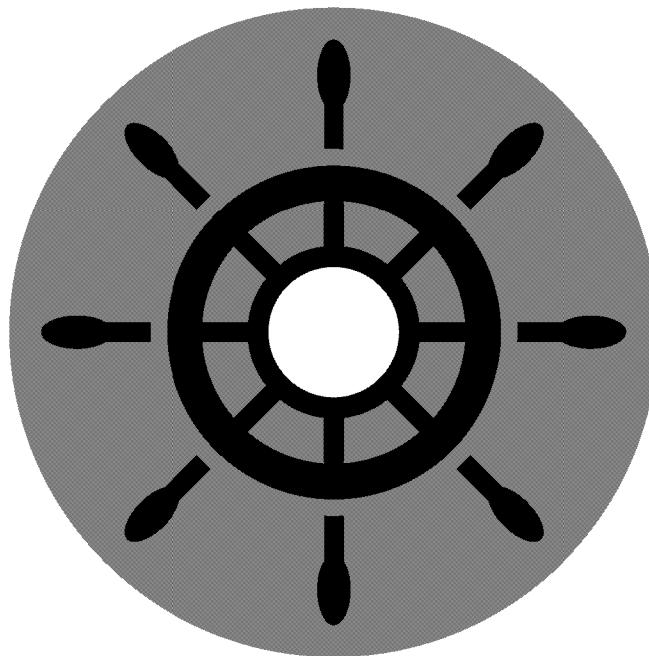
Boards of health care organizations should receive compliance and risk-related information in a format sufficient to satisfy the interests or concerns of their members and to fit their capacity to review that information. Some Boards use tools such as dashboards—containing key financial, operational and compliance indicators to assess risk, performance against budgets, strategic plans, policies and procedures, or other goals and objectives—in order to strike a balance between too much and too little information. For instance, Board quality committees can work with management to create the content of the dashboards with a goal of identifying and responding to risks and improving quality of care. Boards should also consider establishing a risk-based reporting system, in which those responsible for the compliance function provide reports to the Board when certain risk-based criteria are met. The Board should be assured that there are mechanisms in place to ensure timely reporting of suspected violations and to evaluate and implement remedial measures. These tools may also be used to track and identify trends in organizational performance against corrective action plans developed in response to compliance concerns. Regular internal reviews that provide a Board with a snapshot of where the organization is, and where it may be going, in terms of compliance and quality improvement, should produce better compliance results and higher quality services.

As part of its oversight responsibilities, the Board may want to consider conducting regular "executive sessions" (i.e., excluding senior management) with leadership from the compliance, legal, internal audit, and quality functions to encourage more open communication. Scheduling regular executive sessions creates a continuous expectation of open dialogue, rather than calling such a session only when a problem arises, and is helpful to avoid suspicion among management about why a special executive session is being called.

Identifying and Auditing Potential Risk Areas

Some regulatory risk areas are common to all health care providers. Compliance in health care requires monitoring of activities that are highly vulnerable to fraud or other violations. Areas of particular interest include referral relationships and arrangements, billing problems (e.g., upcoding, submitting claims for services not rendered and/or medically unnecessary services), privacy breaches, and quality-related events.

The Board should ensure that management and the Board have strong processes for identifying risk areas. Risk areas may be identified from internal or external information sources. For instance, Boards and management may identify regulatory risks from internal sources, such as employee reports to an internal compliance hotline or internal audits. External sources that may be used to identify regulatory risks might include professional organization publications, OIG-issued guidance, consultants, competitors, or news media. When failures or problems in similar organizations are publicized, Board members should ask their own management teams whether there are controls and processes in place to reduce the risk of, and to identify, similar misconduct or issues within their organizations.



The Board should ensure that management consistently reviews and audits risk areas, as well as develops, implements, and monitors corrective action plans. One of the reasonable steps an organization is expected to take

under the Guidelines is “monitoring and auditing to detect criminal conduct.”¹⁷ Audits can pinpoint potential risk factors, identify regulatory or compliance problems, or confirm the effectiveness of compliance controls. Audit results that reflect compliance issues or control deficiencies should be accompanied by corrective action plans.¹⁸

Recent industry trends should also be considered when designing risk assessment plans. Compliance functions tasked with monitoring new areas of risk should take into account the increasing emphasis on quality, industry consolidation, and changes in insurance coverage and reimbursement. New forms of reimbursement (e.g., value-based purchasing, bundling of services for a single payment, and global payments for maintaining and improving the health of individual patients and even entire populations) lead to new incentives and compliance risks. Payment policies that align payment with quality care have placed increasing pressure to conform to recommended quality guidelines and improve quality outcomes. New payment models have also incentivized consolidation among health care providers and more employment and contractual relationships (e.g., between hospitals and physicians). In light of the fact that statutes applicable to provider-physician relationships are very broad, Boards of entities that have financial relationships with referral sources or recipients should ask how their organizations are reviewing these arrangements for compliance with the physician self-referral (Stark) and anti-kickback laws. There should also be a clear understanding between the Board and management as to how the entity will approach and implement those relationships and what level of risk is acceptable in such arrangements.

Emerging trends in the health care industry to increase transparency can present health care organizations with opportunities and risks. For example, the Government is collecting and publishing data on health outcomes and quality measures (e.g., Centers for Medicare & Medicaid Services (CMS) Quality Compare Measures), Medicare payment data are now publicly available (e.g.,

¹⁷ See USSG § 8B2.1(b)(5).

¹⁸ See USSG § 8B2.1(c).

CMS physician payment data), and the Sunshine Rule¹⁹ offers public access to data on payments from the pharmaceutical and device industries to physicians. Boards should consider all beneficial use of this newly available information. For example, Boards may choose to compare accessible data against organizational peers and incorporate national benchmarks when assessing organizational risk and compliance. Also, Boards of organizations that employ physicians should be cognizant of the relationships that exist between their employees and other health care entities and whether those relationships could have an impact on such matters as clinical and research decision-making. Because so much more information is becoming public, Boards may be asked significant compliance-oriented questions by various stakeholders, including patients, employees, government officials, donors, the media, and whistleblowers.

Encouraging Accountability and Compliance

Compliance is an enterprise-wide responsibility. While audit, compliance, and legal functions serve as advisors, evaluators, identifiers, and monitors of risk and compliance, it is the responsibility of the entire organization to execute the compliance program.

In an effort to support the concept that compliance is “a way of life,” a Board may assess employee performance in promoting and adhering to compliance.²⁰ An organization may assess individual, department, or facility-level performance or consistency in executing the compliance program. These assessments can then be used to either withhold incentives or to provide bonuses

Compliance is an enterprise-wide responsibility.

19 See Sunshine Rule, 42 C.F.R. § 403.904, and CMS *Open Payments*, <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>.

20 Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289, 14,298-14,299 (Mar. 16, 2000).

based on compliance and quality outcomes. Some companies have made participation in annual incentive programs contingent on satisfactorily meeting annual compliance goals. Others have instituted employee and executive compensation claw-back/recoupment provisions if compliance metrics are not met. Such approaches mirror Government trends. For example, OIG is increasingly requiring certifications of compliance from managers outside the compliance department. Through a system of defined compliance goals and objectives against which performance may be measured and incentivized, organizations can effectively communicate the message that everyone is ultimately responsible for compliance.

Governing Boards have multiple incentives to build compliance programs that encourage self-identification of compliance failures and to voluntarily disclose such failures to the Government. For instance, providers enrolled in Medicare or Medicaid are required by statute to report and refund any overpayments under what is called the 60 Day Rule.²¹ The 60-Day Rule requires all Medicare and Medicaid participating providers and suppliers to report and refund known overpayments within 60 days from the date the overpayment is “identified” or within 60 days of the date when any corresponding cost report is due. Failure to follow the 60-Day Rule can result in False Claims Act or civil monetary penalty liability. The final regulations, when released, should provide additional guidance and clarity as to what it means to “identify” an overpayment.²² However, as an example, a Board would be well served by asking management about its efforts to develop policies for identifying and returning overpayments. Such an inquiry would inform the Board about how proactive the organization’s compliance program may be in correcting and remediating compliance issues.

21 42 U.S.C. § 1320a-7k.

22 Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179, 9182 (Feb. 16, 2012) (Under the proposed regulations interpreting this statutory requirement, an overpayment is “identified” when a person “has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.”) disregard or deliberate ignorance of the overpayment.”); Medicare Program; Reporting and Returning of Overpayments; Extensions of Timeline for Publication of the Final Rule, 80 Fed. Reg. 8247 (Feb. 17, 2015).

Organizations that discover a violation of law often engage in an internal analysis of the benefits and costs of disclosing—and risks of failing to disclose—such violation to OIG and/or another governmental agency. Organizations that are proactive in self-disclosing issues under OIG’s Self-Disclosure Protocol realize certain benefits, such as (1) faster resolution of the case—the average OIG self-disclosure is resolved in less than one year; (2) lower payment—OIG settles most self-disclosure cases for 1.5 times damages rather than for double or treble damages and penalties available under the False Claims Act; and (3) exclusion release as part of settlement with no CIA or other compliance obligations.²³ OIG believes that providers have legal and ethical obligations to disclose known violations of law occurring within their organizations.²⁴ Boards should ask management how it handles the identification of probable violations of law, including voluntary self-disclosure of such issues to the Government.

As an extension of their oversight of reporting mechanisms and structures, Boards would also be well served by evaluating whether compliance systems and processes encourage effective communication across the organizations and whether employees feel confident that raising compliance concerns, questions, or complaints will result in meaningful inquiry without retaliation or retribution. Further, the Board should request and receive sufficient information to evaluate the appropriateness of management’s responses to identified violations of the organization’s policies or Federal or State laws.

Conclusion

A health care governing Board should make efforts to increase its knowledge of relevant and emerging regulatory risks, the role and functioning of the organization’s compliance program in the face of those risks, and the flow and elevation of reporting of potential issues and problems to

23 See OIG, *Self-Disclosure Information*, <http://oig.hhs.gov/compliance/self-disclosure-info>.

24 See *id.*, at 2 (“we believe that using the [Self-Disclosure Protocol] may mitigate potential exposure under section 1128J(d) of the Act, 42 U.S.C. 1320a-7k(d).”)

senior management. A Board should also encourage a level of compliance accountability across the organization. A Board may find that not every measure addressed in this document is appropriate for its organization, but every Board is responsible for ensuring that its organization complies with relevant Federal, State, and local laws. The recommendations presented in this document are intended to assist Boards with the performance of those activities that are key to their compliance program oversight responsibilities. Ultimately, compliance efforts are necessary to protect patients and public funds, but the form and manner of such efforts will always be dependent on the organization's individual situation.

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